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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,807	11/30/2001	Jay Short	DVSA-1005US	6627

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,807

Applicant(s)

SHORT ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34,35,114,115,132-154 and 189-201 is/are pending in the application.
4a) Of the above claim(s) 35,132,133,136-139 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/11/2005.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/11/2005 has been entered.

Status of Claims

Claims 31,34,35,114,115,132-154,189-201 are pending.

Claims 35,132,133,136-139 remain withdrawn from consideration as drawn to non-elected species.

Claims 31,34,114,115,134,140-154,189-201 are addressed to the extent they are drawn to the elected species, peptide SEQ ID No. 2, as peptide species, and self-assembly, as the way of polymerizing.

Sequence Listing

The Sequence Listing filed 03/23/2005 was approved by STIC for matters of form.

Information Disclosure Statement

The information disclosure statement filed 04/13/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the references are in

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German and there is no English translation provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Applicants' Information Disclosure Statement filed 04/11/2005 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31,34,114,115,134,140-154,189-201 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for self-assembly of peptide SEQ ID No. 2 itself, does not reasonably provide enablement for self-assembly

of a peptide SEQ ID No. 2 modified by an attachment and/or by substitution of its residues.

Applicant's arguments and second Declaration of Dr. Barton have been considered and deemed to be persuasive-in-part. Examiner accepts statement in the second Declaration of Dr. Barton that Figure 1 reflects micrograph of self-assembled peptide SEQ ID No. 1 and that Fig. 19 describes self-assembly of peptide SEQ ID No. 2 as CanA addressed in the example is peptide SEQ ID No. 2¹. The enablement rejection of record is therefore modified to narrow its scope to scope of enablement.

The claims are drawn not to producing polymers by self-assembly of peptide SEQ ID No.2 itself; rather, the claims as amended are drawn to producing polymers by self assembly of conjugates of SEQ ID No.2 with such various agents as nucleic acids, lipids, "targeting vectors", and derivatives of the above. Even though self-assembly of peptide SEQ ID No. 2 is demonstrated in the specification, it does not reasonably provide enablement for polymers formed from conjugates of said monomeric polypeptide with lipids or nucleotide derivatives, or "targeting vectors" (e.g., oligosaccharides), etc. It is well known that process of self-assembly of polypeptide monomers into polymers depends critically on the structure of the monomers and even slight changes, such as change in length of chain, or addition of ionized residue may change the rate and/or direction of the reaction. See, for example, Urry et al., or

¹ Examiner maintains considerations regarding Example 20, which are now moot in view of acceptance of showing of Example 19. Consequently, applicant's arguments on pages 20-25 of the response are not addressed therein.

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Jenekhe et al. Urry et al discusses that, depending on the structure of the peptide monomer, it can either self-assemble or separate (de-mix). See p. 420. Jenekhe et al. teach that, although many synthetic polymers can organize into segregated mesophases, they might lack rigid sequences and well defined intermolecular interactions². See abstract. Other than general assertions in the specification, there are no examples of any single polypeptide having an attachment such as lipids or nucleotide derivative, or targeting vector³. Nor there is guidance in the specification on polymerization conditions for self-assembly of such conjugate monomers. Much less is there support for self assembly of derivatized peptide SEQ ID No. 2 into such structured polymer formation as peptide tubes or nanoscale delivery vehicles, e.g., nanocages.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Response to arguments⁴

Applicant argues, first, that Urry et al and Jenekhe et al references provide support for the enablement of the instant invention. Examiner disagrees. While the

² i.e., even though some polypeptides can organize into segregated mesophases, they are not forming polymers (as claimed) but form mesophases lacking polymerized sequences.

³ It is noted that, in the discussion of rejection made under USC 112, second paragraph (p. 15 of the response), applicant addresses description on p. 101, lines 12-24 as describing "non-covalent" attachment of lipids. Examiner disagrees: there is no evidence that the lipids become "attached" to polymerizing peptide; nor the term "attachment" is defined in the specification to include non-covalent binding.

⁴ See footnote #1, above

references demonstrate that some molecule can indeed self-associate, they also indicate that self-association critically depends on the structure of the molecules. Thus, Urry et al discusses that, depending on the structure of the peptide monomer, it can either self-assemble or separate (de-mix). See p. 420. Jenekhe et al. teach that, although many synthetic polymers can organize into segregated mesophases, they might lack rigid sequences and well defined intermolecular interactions.

With respect to self-assembly of derivatized peptide SEQ ID No. 2, it seems that applicant attempts to argue, on pages 25-26, that Example 21 demonstrates polymerization of peptide SEQ ID No. 2 with lipids attached to it. However, there is no evidence that even if self-assembly of peptide SEQ ID No. 2 did occur inside liposomes as asserted by applicant, there is no evidence that the lipids of liposomes became attached to peptide SEQ ID No. 2. It is noted that applicant avoids describing polymers allegedly formed in the course of experiment addressed in Example 21 as polymers of a peptide SEQ ID No. 2 with lipids attached to it.

Applicant also states that the term "Pyrotex" used in Fig. 3B is intended to mean a polymer of peptide SEQ ID No. 2. There is no disclosure of such meaning in specification. Further, the term "Pyrotex" is used in the art to describe quite different products such as, e.g., thermal resistance materials. See abstract of Gyrog (AIAA meeting, Jan 19-21, New York, 1970).

Applicant further addresses Exhibit A. As before, there is no Appendix labeled as Exhibit A. If the immunofluorescent light microscope image attached to the Declaration of Dr. Barton is meant, the image submitted to the Office is completely black and it is not possible to detect any meaningful information in it. Note, also that according to the Declaration, the alleged conjugate with green fluorescent protein had been formed under conditions of Example 20, i.e., not by self-assembly but in the

presence of polymer primers, whereas the elected invention is directed to self-assembly. Note also, that had self-assembly of a conjugate of peptide SEQ ID No. 2 with green fluorescent protein been indeed demonstrated, another scope of enablement rejection addressing other "attachments" (such as lipids or nucleotides) would have been issued.

Further, the Declaration and applicant's argument assert that it would be considered a routine experimentation to determine conditions for polymerization of derivatized peptide SEQ ID No. 2. No factual evidence (e.g., references demonstrating state of the art) for such statement is offered. Examiner maintains his position for the reasons stated in the rejection.

Conclusion.

No claims are allowed.

This is an RCE of applicant's Application No. 09/997807. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571)272-0713. The examiner can normally be reached on 9 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Michael Borin
Primary Examiner
Art Unit 1631

mlb